February 24, 2022

Argon Medical Devices, Inc.
Ana Jimenez-Hughes
Sr. Regulatory Affairs Specialist
1445 Flat Creek Road
Athens, Texas 75751

Re: K211798
Trade/Device Name: Cleaner Plus™ Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: January 21, 2022
Received: January 24, 2022

Dear Ana Jimenez-Hughes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211798

Device Name
Cleaner Plus™ Thrombectomy System

Indications for Use *(Describe)*
The Cleaner Plus™ Thrombectomy System is indicated for mechanical de-clotting, aspiration, and controlled and selective infusion of physician-specified fluids, including thrombolytics, in the peripheral venous vasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date Prepared:	February 23, 2022
Company:	Argon Medical Devices, Inc. 1445 Flat Creek Road Athens, Texas 75751 USA Facility Registration number: 1625425
Contact:	Ana Jimenez-Hughes Sr. Regulatory Affairs Specialist Phone: 903-676-4276 Fax: 903-677-9396 Email: ana.hughes@argonmedical.com
Device Trade Name:	Cleaner Plus™ Thrombectomy System
Device Common Name:	Mechanical Thrombectomy Device
Device Classification:	Embolectomy Catheter Product code, QEW/KRA 21 CFR 870.5150 Class II Review Panel: Cardiovascular Devices
Predicate Device(s):	*Primary*: K141617 Rotational Thrombectomy System, Cleaner15/CleanerXT *Reference*: K142870 Indigo Aspiration System
Description of the Device:	The Cleaner Plus™ Thrombectomy System is a single use device used to provide thrombectomy in the peripheral venous vasculature. The device provides additional features, such as aspiration and over-the-wire device placement. The disposable system consists of: (1) the Aspiration Catheter & Dilator, (2) the Handpiece that includes system controls, and an integrated Maceration Wire, and a Peel-Away Introducer and (3) the Aspiration Canister. The Aspiration Catheter with Dilator may be placed over-the-wire to navigate the device to the therapeutic site. The dilator and

guidewire are removed, and the Maceration Wire, using the Peel-Away introducer is advanced through the hemostasis valve of the Aspiration Catheter to the therapeutic site and connected to the handpiece. To complete the system, the provided Aspiration Canister is connected to the handpiece to provide aspiration. The Handpiece provides controls to turn on/off maceration and/or the application of suction. Like the current Cleaner15/CleanerXT devices, mechanical thrombectomy will be achieved by rotating a flexible stainless-steel maceration wire powered by a motor inside the handpiece. The aspiration source is provided to aspirate macerated clot from the distal portion of the device through the handpiece and captures the macerated clot in the Aspiration Canister reservoir. The Aspiration Canister includes a switch to initiate the pump, and LEDs that indicate the level of the vacuum.

Indication for Use:

The Cleaner Plus™ Thrombectomy System is indicated for mechanical de-clotting, aspiration, and controlled and selective infusion of physician-specified fluids, including thrombolytics, in the peripheral venous vasculature.

Technological Characteristics:

A comparison of the technological characteristics of the subject device and the predicate devices shows the Cleaner Plus™Thrombectomy System to be substantially equivalent to the current marketed predicate devices.

Equivalence is established on performance testing in vitro and in vivo, and similarities in indications for use, materials, technological characteristics, principle of operation, design features and sterilization process.

	Subject Device	**Primary Predicate**	**Reference Predicate**
	Cleaner Plus™ Thrombectomy System	**Rotational Thrombectomy System Cleaner15/CleanerXT**	**Penumbra Embolectomy Aspiration System (INDIGO® Aspiration System)**
Manufacturer	Argon Medical Devices, Inc	Argon Medical Devices, Inc.	Penumbra Inc.
FDA Clearance	TBD	K141617	K142870
Class	II	SAME	SAME
Device Classification Name	Embolectomy Catheter Catheter, Continuous Flush	Embolectomy Catheter Catheter, Continuous Flush	Embolectomy Catheter
Regulation	870.5150	870.1210	870.5150
Product Code	QEW/KRA	QEW/KRA	QEW
Clinical Comparison			
Intended Use	Thrombus removal	Thrombus removal	Thrombus removal

	Subject Device	Primary Predicate	Reference Predicate
	Cleaner Plus™ Thrombectomy System	**Rotational Thrombectomy System Cleaner15/CleanerXT**	**Penumbra Embolectomy Aspiration System (INDIGO® Aspiration System)**
Principle of Operation	Inserted percutaneously into the vessel using an introduction catheter, the system Aspiration Catheter and Dilator may be placed over-the-wire to the site of thrombus. The device macerates intra-lumen and wall adherent thrombus with a maceration wire. The macerated thrombus is removed from the vessel using an aspiration system. The aspiration of the clot can be performed simultaneous or independently. The device allows for infusion of physician-specified fluids, including thrombolytics, during the procedure. The infused solution penetrates the clot increasing the effectiveness of the treatment	Inserted percutaneous int the vessel using an introducer sheath. The device macerates intra-lumen and wall adherent thrombus. The sinusoidal wire creates a fluid vortex that effectively macerates thrombus. Contrast media and physician specified solutions, including thrombolytics, may be infused through the catheter lumen to a side hole at the distal end. The dispersion wire uses mechanical rotation to allow the infused solution to penetrate the clot increasing the effectiveness of the treatment. Any residual clot can be aspirated through an introducer sheath prior to restoration of flow.	The INDIGO Aspiration System fundamental mechanism of action is aspiration. Aspiration draws the embolus or thrombus into the Aspiration Catheter to remove the embolus or thrombus from the body. All the Separators function to break up the clot inside of the cathter to make it more amenable to removal from the body via aspiration.
Mechanism of Action	Mechanical maceration and aspiration of thrombus	Mechanical maceration of thrombus	Mechanical aspiration of thrombus
Indication for Use	Indicated for mechanical de-clotting, aspiration, and controlled and selective infusion of physician-specified fluids, including thrombolytics, in the peripheral venous vasculature.	Indicated for (1) mechanical de-clotting of native vessel dialysis fistulae and synthetic dialysis access grafts and (2) mechanical declotting and controlled and selective infusion of physician-specified fluids, including thrombolytics, in the peripheral vasculature.	The Penumbra Embolectomy Aspiration System (Indigo™ Aspiration System) is intended for removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems.
Contraindication	The Cleaner Plus™ Thrombectomy System is contraindicated in the following: • When, in the medical judgment of the physician, such a procedure may compromise the patient's condition. • For infusion of blood or blood products. • In native vessels smaller than 6mm in diameter.	**For the peripheral vasculature** is not to be used: • When in the medical judgment of the physician, such a procedure may compromise the patient's condition. • For peripheral vasculature dilation purposes. • For the infusion of blood or blood products. • In native vessels smaller than 6 mm (Cleaner15 only) • In patients without a vascular filter such as an inferior vena cava.	• Not for use in the coronaries or the neurovasculature.
Single Use	Yes	SAME	SAME
Supplied Sterile	Yes	SAME	SAME
Device Description	The Cleaner Plus™ System consists of: • Cleaner Plus™ Aspiration Catheter with Dilator. • Cleaner Plus™ Handpiece that includes system controls, and an integrated Maceration Wire. • Cleaner Plus™ Aspiration Canister. • The system also includes a peel-away introducer.	Rotational Thrombectomy System Cleaner15/CleanerXT consists of a handpiece unit. Attached to the unit is a sinusoidal shaped tip wire (S-wire). A sliding lever on top of the unit advances and retracts the catheter (6F or 7F). The device has a 3-way side port and a distal side hole on catheter for the infusion of fluids and contrast media	The Penumbra Embolectomy Aspiration System (INDIGO® Aspiration System) is comprised of several devices: • INDIGO Aspiration Catheter • Penumbra Aspiration Pump • IINDIGO Pump/Canister Tubing • INDIGO Aspiration Tubing • INDIGO Separator™.

	Subject Device	Primary Predicate	Reference Predicate
	Cleaner Plus™ Thrombectomy System	**Rotational Thrombectomy System Cleaner15/CleanerXT**	**Penumbra Embolectomy Aspiration System (INDIGO® Aspiration System)**
Technical and Biological Comparison			
Dispersion Wire (rpm)	4000rpm	4000rpm	N/A
Aspiration Catheter Diameter	10F & 12F	6F & 7F	6F, 8F & 12F
Aspiration Catheter Length	65cm & 135cm	65cm & 135cm	85-150cm
Maceration Wire (amplitude)	15mm (uncovered)	9mm & 15mm (uncovered)	N/A
Maceration Wire Diameter	0.035"	0.035" & 0.044"	N/A
Maceration Wire Material	Stainless Steel; Pebax/BaSO4 and Virgin PTFE	Stainless Steel; Pebax/BaSO4, Virgin PTFE	N/A
Reservoir size	400cc	N/A	1000cc
Maximum vacuum	28 inHg	N/A	29 inHg
IEC 60601 Compliance	Yes	SAME	SAME
Performance Testing (In-Vitro)	• Wire – Atraumatic Tip Pull • Wire – Corrosion Resistance • Wire – Fatigue • Wire – Dynamic Retention • Wire – Flexing and Fracture • Wire – Kink • Wire – Tensile Break • Wire – Dimensional • Catheter – Dimensional • Catheter – Aspiration Tip Collapse • Catheter – Kink • Catheter – Hemostasis Valve Leak • Catheter – Torsional Break • Catheter – System Leak • Catheter – Tensile Break • Shipping Qualification • Luer Functional • Catheter – Coating Performance and Integrity • IEC 60601 Compliance • Canister & Dead Volume Study • Pump Functionality - Relief Valve • Pump Tubing – Pull • Pump Performance • Pump – Button Press Endurance • Simulated Use • Handpiece Dimensional • Handpiece Motor & Battery Performance • Pump Battery Performance • Handpiece – Functionality • Handpiece – Peel-away Introducer • Luer Dimensional • Radiopacity • Functional, Performance, and Software Testing • Float Valve Study	• Wire Break Test • Wire Fatigue Test • Gelatin Test • Graft Abrasion • Kink/Resiliency • Shape Retention • Wire Tensile Test • Torsion Test • Valve Compression • Vessel Energy	• Visual & Dimensional • Tensile Strength • Bond Strength • Hub Aspiration test • Burst Test • Particulate Test • Coating Integrity Test • Flexibility Test • Kink Resistance Test • Ovalization Resistance Test • Friction Test • Flow Rate Test • Elongation Test • Corrosion Test • Torsion Test • Simulated Use Test • Leak Test • Clot Removal Test • Vacuum Collapse Test • Trackability Test

	Subject Device	Primary Predicate	Reference Predicate
	Cleaner Plus™ Thrombectomy System	**Rotational Thrombectomy System Cleaner15/CleanerXT**	**Penumbra Embolectomy Aspiration System (INDIGO® Aspiration System)**
Non-Clinical, Animal Study	Yes	Yes	Yes

Biological Comparison	• Cytotoxicity (ISO 10993-5)
	• Sensitization (ISO 10993-10)
	• Irritation or Intracutaneous Reactivity (ISO 10993-10)
	• Material Mediated Pyrogen (ISO 10993-11)
	• Acute Systemic Toxicity (ISO 10993-11
	• Hemocompatibility (ISO10993-4)
	  ○ In-vitro Blood Assay
	  ○ Complement Activation, SC5b-9
	  ○ Heparinized Platelet and Leucocyte Counts
	  ○ Partial Thromboplastin Time (PTT)
	  ○ ASTM Hemolysis Assay, Direct and Extract Methods (ISO)
		• Cytotoxicity (ISO 10993-5)
		• Sensitization (ISO 10993-10)
		• Irritation or Intracutaneous Reactivity (ISO 10993-10)
		• Material Mediated Pyrogen (ISO 10993-11)
		• Acute Systemic Toxicity (ISO 10993-11
		• Hemocompatibility (ISO10993-4)
		  ○ C3a Complement Assay
		  ○ Complement Activation, SC5b-9
		  ○ ASTM Partial Thromboplastin Time (PTT)
		  ○ ASTM Hemolysis
		• Genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3).
			• Cytotoxicity (ISO 10993-5)
			• Sensitization (ISO 10993-10)
			• Irritation or Intracutaneous Reactivity (ISO 10993-10)
			• Acute Systemic Toxicity (ISO 10993-11
			• Hemocompatibility (ISO10993-4)
			  ○ Complement Activation
			  ○ Hemolysis
			  ○ Coagulation - PT
			  ○ Coagulation – PTT
			  ○ In vivo thrombogenicity
			• Material Mediated Pyrogen (ISO 10993-11)
			• Genotoxicity
			  ○ Mouse Lymphoma Mutagenesis Assay – ISO
			  ○ Ames test
			  ○ Micronucleus Assay

Packaging Configuration	1) Aspiration Catheter and Dilator are sealed in a Tyvek pouch. Pouch placed in a shelf carton. 2) Handpiece with Maceration Wire is placed in a base tray with lid and then sealed in a Tyvek pouch. Pouch placed in a shelf carton. 3) Aspiration Canister is placed in a base tray with lid and then sealed in a Tyvek pouch. Pouch placed in a shelf carton. 4) All the individual system components are placed in a single labeled shipper box. Packaging materials are commonly used for medical devices.	Handpiece is placed in a base tray with lid and then sealed in a Tyvek pouch. Pouch is placed in a shelf carton. Packaging materials are commonly used for medical devices.	Individually packed components. Packaging materials are commonly used for interventional devices
Sterilization	Minimum SAL 10^{-6}, EtO	Minimum SAL 10^{-6}, EtO	Minimum SAL 10^{-6}, EtO
Shelf-Life	6 months	36 months	36 months

Non-Clinical Data (Bench-top Testing):

No performance standards have been established under section 514, performance standards, of the Food, Drug and Cosmetic Act for these devices.

A series of testing was conducted in accordance with protocols based on requirements outlined in guidance and industry standards and the below were shown to meet the acceptance criteria that were determined to demonstrate substantial equivalence.

The following tests were performed under the specified testing parameters to support the Cleaner Plus™ Thrombectomy System substantial equivalence:

- Wire - Atraumatic Tip Pull
- Wire - Corrosion Resistance
- Wire - Fatigue
- Wire - Dynamic Retention
- Wire - Flexing and Fracture
- Wire - Kink
- Wire - Tensile Break
- Wire - Dimensional
- Catheter - Dimensional
- Catheter - Aspiration Tip Collapse
- Catheter - Kink
- Catheter - Hemostasis Valve Leak
- Catheter - Torsional Break
- Catheter - System Leak
- Catheter - Tensile Break
- Shipping Qualification
- Luer Functional
- Luer Dimensional
- Catheter - Coating and Performance and Integrity
- Software Validation
- IEC 60601 Compliance
- Canister & Dead Volume Study
- Pump Functionality - Relief Valve
- Pump Tubing – Pull
- Pump Performance
- Pump Button Press Endurance
- Simulated Use
- Handpiece Motor & Battery Performance
- Pump Battery Performance
- Handpiece Dimensional
- Handpiece – Functionality
- Handpiece – Peel-away Introducer
- System - Vacuum Decay
- Radiopacity
- Functional, Performance, and Software Testing
- Float Valve Study

Non-Clinical Data Biocompatibility

Biocompatibility is established for the Cleaner Plus™ Thrombectomy System according to ISO 10993-1:2018 as an external communicating, circulating blood with limited duration <24hrs.

All studies were performed following the approved protocol under Good Laboratory Practices (GLP) in compliance to FDA GLP, 21 CFR Part 58.

<u>Biocompatibility Testing included:</u>

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation or Intracutaneous Reactivity (ISO 10993-10)
- Acute Systemic Toxicity (ISO 10993-11)
- Material Mediated Pyrogen (ISO 10993-11)
- Acute Systemic Toxicity (ISO 10993-11
- Hemocompatibility (ISO10993-4)
    - In-vitro Blood Assay

	○ Complement Activation, SC5b-9 ○ Heparinized Platelet and Leucocyte Counts ○ Partial Thromboplastin Time (PTT) ○ ASTM Hemolysis Assay, Direct and Extract Methods (ISO)
Non-Clinical - Animal Study	An animal study was performed to assess substantially equivalent safety and performance outcomes of the Cleaner Plus™ Thrombectomy System on vascular endothelium by evaluating for vessel patency, clot burden, and clinically significant pulmonary embolism after thrombectomy in the peripheral vasculature. There were no histological signs of thromboembolism noted in the treated vessels, there were no ruptures, hemorrhage, perforation, or dissection noted histologically in the treated veins. All the end points of this study were met and there are no new questions of safety or effectiveness.
Substantial Equivalence:	Based on the Indication for Use, design, and non-clinical bench and animal testing, the Cleaner Plus™ Thrombectomy System meets the requirements for its intended use and is substantially equivalent to the predicate devices.
Conclusion:	The Cleaner Plus™ Rotational Thrombectomy System introduces no additional clinical risk, based on its comparable indication for use and mechanism of action. Based on performance testing in vitro and in vivo, and similarities in indications for use, materials, technological characteristics, principle of operation, design features and sterilization process; the Cleaner Plus™ Thrombectomy System is substantially equivalent to the predicate devices.